Consumer and Corporate Affairs Canada
Consommation et Corporations Canada

(11) (A) No. 1 205 602

(45) ISSUED 860610

(52) CLASS 3-109

(51) INT. CL.^{4} A61F 1/00

(19) (CA) CANADIAN PATENT (12)

(54) Prosthesis for Tensile Load-Carrying Tissue

(72) Bruchman, William C.;
Bolton, Carl W.,
U.S.A.

(73) Granted to Gore (W.L.) & Associates, Inc.
U.S.A.

(21) APPLICATION No. 436,411

(22) FILED 830909

(30) PRIORITY DATE U.S.A. (416,600) 820910

No. OF CLAIMS 12

Canada

ABSTRACT OF THE DISCLOSURE

The inventive article is a ligament or tendon prosthesis having multiple longitudinally parallel strands of microporous expanded polytetrafluoroethylene, the individual strands having an average porosity greater than 30% in the areas requiring tissue ingrowth. Additionally, strand dimensions and microstructure are selected so that tissue can penetrate throughout. The prosthesis is formed from multiple loops of a single continuous filament. Densified eyelets are formed in the loop for mounting to bone. The strands are twisted 180° or arranged in a loose braid about the prosthesis axis for improved load distribution during bending of the prosthesis.

FIELD OF THE INVENTION

The inventive article described herein is a synthetic prosthesis for replacement or repair of ligaments or tendons.

DESCRIPTION OF THE PRIOR ART

The generally accepted method of repair of ligaments and tendons is through the use of tissue transplanted to the defect site from elsewhere in the body. This method of repair often fails due to a number of factors, including insufficient strength of the transplanted tissues, dependence of the transplanted tissue on revascularization for viability, and inadequate strength of attachment or fixation of the transplanted tissue.

A great need exists for a prosthetic device to replace damaged ligaments and tendons, and there have been a number of previous attempts at providing such devices. However, there is no prosthesis today which is widely accepted. Among the reasons for failure of prosthetic devices are inadequate tensile strength, lack of adequate fixation, deterioration of the device due to mechanical stresses, and deterioration of the prosthesis/tissue interface.

Previous methods of attachment to bone and soft tissues which have been attempted include:

U.S. Pat. Nos. 3,971,670, 4,127,902, 4,129,470, 3,992,725, and 4,149,277. These patents teach attachment through tissue ingrowth into porous surfaces of the prosthetic device.

U.S. Pat. Nos. 3,613,120, 3,545,008, and 4,209,859. These patents teach methods of tissue attachment to porous fabrics with various methods of maintaining apposition to the repaired tissue.

U.S. Pat. Nos. 3,896,500, 3,953,896, 3,988,783, and 4,301,551. These patents teach attachment to bone by means of rigid mechanical devices such as screws, threads or other devices.

SUMMARY OF THE INVENTION

One objective of this invention is to maximize tissue attachment strength to the prosthesis without sacrificing prosthetic strength. As described, this is accomplished through the use of multiple microporous PTFE strands possessing the required characteristic interstitial dimension. An additional object of this invention when used as a prosthetic ligament is to provide an initial means of fixation of the device which allows the patient nearly immediate mobility. This reduced interval of immobility has the effect of greatly reducing required rehabilitation time for the affected joint.

To achieve the foregoing objects and in accordance with the present invention as embodied and broadly described herein, the tensile load-bearing tissue prosthesis comprises, in the portion wherein attachment to tensile force-applying tissue is required, a plurality of longitudinally adjacent parallel strands of microporous PTFE having a characteristic interstitial dimension and a strand thickness sufficient to permit tissue material ingrowth across substantially the entire strand thickness.

Preferably, the material is expanded polytetrafluoroethylene having a microstructure of interconnecting voids defined by nodes and fibrils, and having a characteristic interstitial dimension of greater than about 7u, and a matrix tensile strength of greater than about 20,000 psi and with a porosity greater than 30%.

It is further preferred that the parallel strands are formed from a plurality of concentric loops of a continuous filament of the material, the loops being elongated in the tensile load direction, and wherein the ends of the plurality of elongated loops are gathered and bonded together to form at least one eyelet for attaching the article to tensile force-applying bone tissue.

It is further preferred that the prosthesis includes means for distributing the tensile load among the individual strands.

This invention will be further understood by reference to the drawings which are given for illustration only and are not intended to limit the scope of the invention but which are to be read in conjunction with the specifications.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a graph showing log stabilized tissue ingrowth and log maximum strand thickness of the prosthesis of the present invention, as a function of characteristic interstitial dimension;

Figure 2 is a photomicrograph of the PTFE material used in the construction of the prosthesis of Example B;

Figure 3 is a photomicrograph of the PTFE material used in the construction of the prosthesis of Example C;

Figure 4 is a photomicrograph of the material of Figure 3 laterally stretched to provide for measurement of characteristic interstitial dimension;

Figure 5 shows a schematic perspective view of one prosthesis constructed in accordance with the present invention;

Figure 6 depicts schematically the implantation of an anterior cruciate ligament prosthesis not constructed in accordance with the present invention;

Figure 7 depicts schematically a stage in one method of construction of a prosthesis of the present invention;

Figure 8 shows a schematic perspective view of another prosthesis constructed in accordance with the present invention;

Figure 9 depicts schematically a stage in another method of construction of a prosthesis of the present invention;

Figure 10 depicts schematically a perspective view of yet another prosthesis constructed in accordance with the present invention; and

Figures 11A, B, and C depict the implantation of the prosthesis of Figure 8 into a knee joint as an anterior cruciate ligament prosthesis.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The inventive article described herein is a synthetic prosthesis for replacement or repair of ligaments or tendons. The prosthesis is made up of multiple strands of porous PTFE. The porosity of the strands is characterized by interconnecting void space throughout. Strand dimensions are small enough to permit tissue growth in and through the entire strand. The percent void space, or porosity, is greater than 30%, which allows mechanical attachment of tissue in the interstitial spaces of the prosthesis to provide sufficient attachment strength. This degree of porosity is a requirement only for those sections of the device which are intended to be anchored through tissue fixation. Porosity, as used here, is defined as;

$$\% \text{ Porosity} = \left[1 - \frac{\rho_2}{\rho_1}\right] 100$$

where: ρ_2 = density of porous material

ρ_1 = density of solid PTFE making up the solid content of the porous material. For PTFE which has never been sintered $\rho_1 = 2.3$ gm/cm^3 and for materials which have been sintered a value of 2.2 gm/cm^3 is used for ρ_1, although this value can actually vary somewhat depending on sintering and cooling conditions.

Immediate postoperative attachment of the device is provided by eyelets which are attached directly to bony tissue. This initial attachment is augmented and finally made redundant as tissue grows into the porous strand material, providing permanent attachment of the prosthesis to tissue. Tissue can easily grow between and among the strands since they are not attached to each other nor held together tightly. However, the depth to which tissue can grow into each strand is governed by the dimensions of the interconnected void corridors or pathways through the porous microstructure. The complex intercommunicating void space is formed by the solid PTFE matrix. In some cases, the matrix is made up of large solid nodes interconnected by long flexible, relatively inelastic fibrils. Although the nodes may present rigid inflexible structures to ingrowing tissue, the fibrils can be bent and pushed aside by penetrating tissue. Other microstructures of this invention have much smaller nodes which appear merely as connection points for the fibrils. In both cases, the strength of the fibrils in tension is very high, and although they can be bent by tissue, they cannot be stretched significantly. The microstructures of this invention can be characterized by a mean interstitial dimension which can be used to predict the depth of tissue

ingrowth. Short fibril lengths impede and bottleneck tissue invasion. Thus, for porous strands having short fibril lengths, the overall strand dimension must itself be small enough so that ingrowth and attachment will occur throughout the entire strand.

The methods used here to characterize the fibril length of a particular microstructure rely on visual examination of that microstructure. Photographs at a convenient magnification can be provided through scanning electron microscopy or, in some cases, light microscopy. The microporous PTFE materials of this invention can vary sufficiently in their microstructure so that different techniques of measuring the characteristic interstitial dimension must be used. Strand fibers such as those made by the process described in Example B possess a microstructure which can clearly be characterized by nodes interconnected by fibrils. The characteristic interstitial dimension for materials of this type can be determined through a direct measurement of the spacing between nodes. This measurement is taken along a line placed in the direction of strength orientation (Figure 2). A large enough number of measurements must be taken so that the node spacing is adequately characterized. The mean node spacing thus provided is used to characterize the interstitial space and thereby predict the depth of ingrowth into that microstructure.

In strand material which has been manufactured by a stretching process such as is described in U.S. Pat. No. 3,962,153, or the products of U.S. Pat. No. 4,187,390, the nodes of PTFE can be smaller and much less defined. In highly stretched products made according to these patents, node spacing becomes very large and fibrils are packed together. The sintering step in production of these materials causes the bundles of fibrils to coalesce and form secondary attachment points. For this reason, the microstructure of such materials is not readily apparent even under magnification. In determining the characteristic interstitial dimension of these materials, it is necessary to measure the distance between fibril suspension points rather than measuring the fibril length (i.e., node spacing). The interstitial dimensions of these materials can be observed if samples are prepared for microscopy by slightly stretching the material at right angles to its direction of strength orientation. Upon stretching the sample 10% in the lateral direction, with the sample restrained from shrinking in the longitudinal direction, the points at which fibrils are connected become apparent under microscopic examination. The distance between fibril connections is then measured at all obvious gaps created between fibril bundles. This measurement is taken in the direction of strength orientation. As with the method described previously for node spacing, the number of measurements of fibril suspension distance must be sufficient to characterize interstitial dimensions of the microstructure.

Figure 3 shows how material of this type appears without lateral stretching as compared to Figure 4 which is a micrograph of the same material with 10% lateral stretching. This lateral stretching, which is used only to characterize the microstructure of the material, represents a temporary structural reorientation. A force placed on the material in the longitudinal direction causes a return to the original lateral dimension and a restoration of the original microstructure. As previously described, it is believed that the fibrils composing this microstructure are pushed aside by ingrowing tissue. The method of measuring the characteristic interstitial dimension for materials of this type is shown in Figure 4. Having once determined the characteristic interstitial dimension by the techniques described, the proper strand dimensions can be determined.

Figure 1 presents the relationship between characteristic interstitial dimension and depth of ingrowth of tissue into the microporous strands of the articles of this invention. The abscissa of Figure 1 refers to the ultimate depth to which tissue may penetrate a microstructure of indicated characteristic interstitial dimension regardless of implant time. The relationship is derived from numerous experimental observations of various kinds of implanted devices, all of which were composed of porous PTFE which had been manufactured according to the teachings of U.S. Pat. No. 3,953,566, U.S. Pat No. 3,962,153 or as described in Example B.

The maximum strand thickness which would allow tissue penetration through the entire strand is approximately two times the tissue penetration depth. The maximum strand thickness is presented as the right-hand ordinate of Figure 1. Thickness, as used here, refers to the appropriate minor cross-sectional dimension of a strand, e.g., the diameter of a strand of circular cross-section, the thickness of a strand of rectangular cross-section. In general, combinations of characteristic interstitial void dimension and strand thickness which fall underneath the curve are preferred because they allow complete tissue penetration across the strand cross-section in a shorter time interval. The preferred combinations may be determined from the following relationships.

$\ln$ (strand diam) $\leq 2.28 \times 10^{-2}$ (CID) - 4.36

for CID > 7u, $\leq$ 120u

$\ln$ (strand diam) $\leq 6.98 \times 10^{-2}$ (CID) - 9.94

for CID $\geq$ 120u

where: CID = characteristic interstitial dimension (microns)

ln = natural logarithm

strand diameter is expressed in inches

The depth of tissue penetration into the microporous structure decreases radically as characteristic interstitial dimension falls below 10 microns. This decrease is due to the fact that in structures with this characteristic spacing and below, only a small number of the interstitial pathways are large enough to admit a single cell of the desired type. At characteristic interstitial dimensions of 120u and greater, substantial vascularization accompanies tissue ingrowth and allows for a greatly increased depth of penetration. We believe that this creates a slope increase in the relationship of interstitial dimension and depth of tissue penetration as shown in Figure 1.

A major requirement for a successful ligament or tendon prosthesis is that of adequate strength. In many situations prosthetic materials used to replace these natural structures are subjected to very high tensile loads. The strength of the prosthesis must in some cases be many times that of the peak load to which it will be exposed to compensate for the mechanical properties of the prosthesis which are time-dependent.

From a mechanical strength standpoint, one of ordinary skill in the art would realize that the number of individual strands needed for a particular application will depend on several factors. These include: the individual strand cross-sectional area; the tensile strength of the individual strand; and the tensile force requirement for that particular application, including any safety factors for creep strain limitations. The individual strands used in this invention can be constructed using the processes described in U.S. Pat. No. 3,953,566, U.S. Pat No. 3,962,153 or following Example B. It is desirable to use a high matrix tensile strength material in order to minimize the overall physical dimensions of the device and thereby minimize the size of drill holes placed in the bone to mount the device. Matrix tensile strength refers to the strength of the polymer in a porous specimen and is used as defined in U.S. Pat No. 3,953,566.

In the preferred form of this invention:

--The strand material is porous PTFE with a matrix tensile strength greater than 20,000 psi, a porosity greater than 30%, and a microstructure characterized by intercommunicating pathways formed by the boundaries of nodes and fibrils.

--Strand dimensions and characteristic interstitial dimensions of the microstructure are selected such that tissue ingrowth throughout the strand takes place in a rapid fashion.

--Each strand and the finished construction possess sufficient strength necessary to meet the mechanical requirements of the particular application.

--The parallel strands result from multiple loops formed from a continuous filament of the strand material.

--The ends of the multiple loops are gathered and formed into at least one eyelet for attaching the article to bone tissue.

--The uniformity of strand loading of the prosthesis under tensile force is enhanced through:

1. Minimizing differences in loop length used to form the parallel strands.

2. Compression of the loop strands in the eyelet segments at an elevated temperature sufficient to coalesce the material and provide strand-to-strand adhesion.

--The prosthesis also includes means for distributing the tensile load among the strands as it passes around a radius, said means including:

1. A twist in the strand bundle about its longitudinal axis.

2. A loose strand braid.

--Although the ligament prosthesis embodiment in Figure 10 is shown with a pair of opposing eyelets formed from elongated loops, the present

invention also encompasses a single eyelet 324 formed in the loops gathered for attachment to bone. The loops at the other end 316 remain ungathered or splayed to provide attachment to soft tissue such as muscle tissue, as by suturing (see Figure 5). In this latter case, the closed loop ends provide additional resistance to possible strand slippage past the sutures. The single eyelet embodiment of this prosthesis 310, could find use in the repair or replacement of tendons.

EXAMPLE A

This example demonstrates a prosthetic device which did not achieve satisfactory system strength because the strand thickness was too large for the interstitial dimension which characterized its microstructure. The strand thickness (diameter) was 0.26 inches, porosity of the strand was approximately 80%, and the characteristic interstitial dimension was about 78 microns. This interstitial dimension was determined as shown in Figure 2. The prosthesis was used to replace the anterior cruciate ligament of a dog by routing the material through drill holes in the tibia and femur. Four holes were drilled in the tibia 2 and femur 4 such that the prosthesis strand 6 formed a loop of material with two strands in the position of the original ligament (Figure 6). Initial fixation was provided by tying the ends of the strand together in a knot 8 to form a continuous loop. Ingrowth and formation of tissue within the interstices of the microporous material were expected to augment the initial fixation strength and to distribute stresses to the surrounding tissue. Each of the strands crossing the knee joint possessed a tensile strength of about 550 pounds. The combined strength of these two strands was then 1,100 pounds. After having been implanted for 260 days, the knee joint was explanted.

Drill holes were placed in the tibia and femur for mounting into tensile test clamps. After removal of all supporting collateral structures about the knee, the femur was distracted from the tibia along the axis of the prosthetic ligament at a constant rate of 500mm per minute until failure. The length spanning the intra-articular space between bone tunnels represented that portion of the prosthesis placed under tensile load during the test, due to tissue attachment to the prosthesis in the bone tunnels. The failure mode of the system was rupture of the prosthetic device at the level of exit from the bone tunnels. Surprisingly, this rupture took place at a value of only 200 lbs. Through histological inspection, we discovered that this reduction in strength was related to the restriction of bony ingrowth to generally less than 1mm depth into the prosthesis. With a strand of this diameter and characteristic interstitial dimension, attachment takes place only at a circumferential ring of material on the periphery of the device. This reduced area then becomes the only load-bearing material of the prosthesis as a tensile force is initially applied. Failure occurs in this circumferential ring of material first and then progresses through the central portion of the prosthesis.

EXAMPLE B

The experience cited in Example A led to the discovery that tissue ingrowth must penetrate throughout the cross-section of the strand in order to provide adequate long-term system strength. Accordingly, a device was constructed using a strand of similar porosity and characteristic interstitial dimension but with a much smaller diameter. The strand material used to construct the anterior cruciate ligament prosthesis of this example was made as follows:

PTFE dispersion powder ("Fluon* CD 123" resin produced by ICI America) was blended with 130cc of "ISOPAR* K" odorless solvent (produced by Exxon Corporation) per pound of PTFE, compressed into a pellet, and extruded into a 0.108 inch diameter rod in a ram extruder having a 96:1 reduction ratio in a cross-section from the pellet to the extruded rod.

The extruded rod still containing Isopar K was immersed in a container of Isopar K at 60°C and stretched to 8.7 times its original length between capstans with an output velocity of about 86.4 ft/min. These capstans were about 2.8 inches in diameter with a center-to-center distance of about 4.5 inches. The diameter of the rod was reduced from about 0.108 inch to about 0.047 inch by this stretching. The Isopar K was then removed from this stretched material.

The stretched rod was then pulled through a circular densification die heated to 300°C. The opening in the die tapered at a 10° angle from about 0.050 inch to 0.025 inch and then was constant for about 0.025 inch length. The output velocity of the material exiting the die was 7.2 ft/min.

The stretched rod was then heated to 300°C through contact with heated, driven capstans and stretched 4 1/2 fold (350%) with an output velocity of 6.5 ft/min. These capstans had a diameter of 2.75 inches and a center-to-center distance of 4.5 inches.

Finally, the rod was restrained from shrinking and exposed to about 367°C in an air oven for 30 seconds.

In the finished form, the fiber made with this process possessed the following characteristics:

Diameter = 0.026 inches
Matrix Tensile Strength = 74,000 psi
Porosity = 80.8%
Characteristic Interstitial Dimension = 74u

As illustrated in Figure 7, prosthesis 10 was constructed on two steel spools 42, 44 which were mounted on a rack (not shown). The spools were supported on studs 46, 48 spaced 14cm from center line to center line. These steel spools were threaded to allow demounting of one flange. The strand of PTFE material was passed around these two spools 80 times so that a total of 160 strands connected the two spools. The two free ends of the fiber were tied together with multiple square knots. One spool was demounted from the stud, rotated through 180° and remounted on the stud, thus imparting a

* Trademark

one-half twist about the longitudinal axis of the construction. The construction was then wrapped with a thin film of PTFE a total of 25 revolutions each at three locations. This film was manufactured according to the teachings of U.S. Pat. No. 3,962,153 and had the following characteristics:

Width = 0.375"
Thickness = 0.00025"
Longitudinal matrix tensile strength = 70,000 psi
Porosity = 84%

The bundle of strands was wrapped with this thin film at two points 28, 30 adjacent to the spools 42, 44 thereby forming eyelets 24, 26 at the ends of the construction (Figure 8). A central portion 38 was also wrapped with film. The two spools were then demounted from the studs and placed on a rack constructed of thin metal wire designed to prevent rotation and longitudinal shrinkage. This rack was then exposed to 375°C in an air oven for six minutes. After cooling, the spools were demounted from the ends of the construction. The position occupied by the spools provided eyelets through which this ligament prosthesis construction can be attached to bone with screws or other suitable means of fixation. All areas which had been wrapped with film had become compressed during the heating treatment due to film shrinkage, thereby providing strand-to-strand cohesion. During the previously described heating cycle, some fiber-to-fiber attachment in the unwrapped regions also took place. These fibers were then individually separated using a metal pick. The construction then comprised 160 microporous PTFE strands connecting two eyelets of somewhat densified material. 'Prosthesis 10 included a 180° twist along the tensile load direction to better distribute the tensile load among strands 20. PTFE tape wrap 38 surrounding strands 20 and positioned approximately midway between ends 14, 16 of prosthesis 10 serves to maintain the twist by securing strands 20 against untwisting during implantation. As with PTFE wraps 28, 30, wrap 38 is intended to be positioned outside of the bone contact area so as not to inhibit tissue ingrowth into strands 20.

A device prepared in the manner just described was implanted into the knee of a sheep to replace the excised host anterior cruciate ligament (see Figures 11A, B and C). This implantation was accomplished through the placement of one 1/4" drill hole in both the tibia and femur. The placement of the hole in the tibia was along the axis of the previously removed natural anterior cruciate and exited at the insertion site. The placement of the femoral drill hole began at the lateral distal femoral surface proximal to the femoral epicondyle. The tunnel was angled such that the exit hole was created just proximal to the lateral femoral condyle on the popliteal surface of the femur. The prosthesis 10 was routed from the femoral exit site through the intercondylar space, across the intra-articular space, and through the tibial tunnel. The eyelets 24, 26 and wrapped segments 28, 30 at the end of the construction were positioned to be to the outside of the drilled bone tunnels. The placement of the wrapped segment 32, 34 and 38 at the center region of the construction was in the intra-articular space. The prosthesis 10 was then anchored to bone with self-tapping orthopedic screws placed through the eyelets 24, 26. The knee joint was determined to be stable immediately after the operation.

After three months implant time, the knee was removed from the animal and drill holes placed in the tibia and femur into which clamps were mounted to provide for tensile testing along the axis of the ligament construction. After removal of muscle tissue and severing of all supporting collateral structures about the knee, the femur was distracted from the tibia at a constant rate of 500mm per minute until failure. System failure took place at 642 lb. The failure took place in the ligament prosthesis at the eyelet secured to the femur. Rupture took place as the load exceeded the fixation provided by tissue ingrowth into the intra-osseous segments and was transferred to the fixation screw. Device failure was related to an unwinding of the strand material through the eyelet segments after several strands had failed. Histologic inspection of this sample showed tissue ingrowth among and into the strands. Tissue ingrowth had proceeded completely through the diameter of some strands. We anticipate that with longer implant times the majority of strands would have shown complete and thorough ingrowth.

EXAMPLE C

The thin film of expanded PTFE used as strand material in this embodiment was obtained from W. L. Gore and Associates, Inc., Fibers Division, Three Blue Ball Road, Post Office Box 1010, Elkton, Maryland, 21921, under the part number Y10383. This film had the following properties:

Width = 0.25"
Thickness = 0.0010"
Matrix Tensile Strength = 93,400 lb/in^2
Porosity = 50%
Characteristic Interstitial Dimension = 11.0u

The mode of failure of the prosthetic ligament as described in Example B led to the observation that improved strand-to-strand cohesion was desirable in the eyelet region. Accordingly, a construction method somewhat modified from that of Example B was employed for the prosthesis 110 shown in Figure 10.

Four spools 141, 142, 143, and 144 were mounted on a rack (not shown) on which the spools were supported by studs 145, 146, 147, and 148 positioned so as to form a 9cm x 5cm rectangle (Figure 9). These steel spools were threaded to allow demounting on one flange. The strand of PTFE material was passed around these four spools a total of 60 times. The strand of thin PTFE material was twisted about its longitudinal axis 20 times during each complete circumference around the four spools. The free ends of the continuous strand were then tied together at a point midway along one of the 5cm bundle sides.

A 3.5cm segment midway in each of the 5cm sides at point 150, 152 was then compressed in a sizing die to a rectangular cross section of 0.058" x 0.150". During compression, this sizing die was heated to 360°C and immediately allowed to cool. This precompression stage is necessary to facilitate the placement of the construction in an eyelet compression die. The central 1 inch segment of the precompressed region was then wrapped with 25 revolutions of a thin film of PTFE 160. This film was manufactured according to the teachings of U.S. Pat. No. 3,962,153 and had the following characteristics:

Width = 0.375"
Thickness = 0.00025"
Longitudinal Matrix Tensile Strength = 70,000psi
Porosity = 84%

The device was then demounted and placed on a two-post rack with two steel pins placed 14cm center to center (similar to Figure 7) with the precompressed, film wrapped segments centered about the pins. With reference to Figure 10, the two parallel precompressed segments were gathered adjacent to each pin and wrapped at point 128, 130 a total of 25 times with the thin film of expanded PTFE of the type described above. Both ends 114, 116 of the construction were placed into the final eyelet-forming die. The eyelets 124, 126 were then compressed within the die to a specific gravity estimated by calculation to be 2.2, heated immediately to 360°C for 10 minutes, and then cooled. Following removal from the eyelet-forming dies, the construction was remounted on a two-post rack with a 180° twist about the longitudinal axis of

the device. A 0.4" segment 138 midway between the eyelets 124, 126 was then wrapped tightly with 25 circumferential layers of the thin film described previously and compressed in a heated cylindrical die to a specific gravity calculated to be 2.2. It was held compressed at 360°C for ten minutes and then cooled and removed from the die. Referring to Figure 10, the construction then comprised 120 microporous PTFE strands 120 connecting two eyelets 124, 126 formed of densified strand material and multiple layers of PTFE film. The purpose of the compressed eyelet area was to maintain integrity of the remaining strands should one or more strands be severed. This densification also provides for more uniform strand loading under tensile forces. The purpose of the 180° twist in the strand bundle was to provide for more uniform strand loading as the implanted bundle passes around the radius of the femoral condyle in the intercondylar space. The purpose of the compressed segment in the center of the strand bundle was to help preserve the 1/2 twist during implantation. We believe that a loose braid in the strands, oriented about the longitudinal axis, will also serve to distribute the tensile force among the strands and could be substituted for the 180° twist. One of ordinary skill in the art would know how to construct a loose strand braid.

The device prepared in the manner just described was implanted into the knee of a sheep to replace the excised host anterior cruciate ligament. This implantation was accomplished using the techniques previously described in Example B (see Figure 11). After six months implant time, the reconstructed knee will be removed and tensile tested in the manner previously described. The anticipated result of this test is that the tensile strength of the system will be at least 600 pounds unless unrelated bone failure occurs prior to failure of the ligamentous reconstruction. It is further anticipated that this level of tensile strength will be achieved through the presence of tissue attachment to the individual fibers contained within the bone tunnels. Upon histologic inspection, it is anticipated that at six months post-implantation, substantial tissue formation will be observed among and penetrating into the individual strands.

WHAT IS CLAIMED IS:

1. Article of manufacture for use as a tensile load-bearing tissue prosthesis for connection between tensile force-applying tissues comprising, in the portion wherein attachment to the tensile force-applying tissue is required, a plurality of longitudinally adjacent parallel non-adhering strands of microporous polytetrafluoroethylene material having interconnecting voids defined by nodes and fibrils, the thickness of each of said strands being chosen in relation to the microstructure of said material such that tissue ingrowth can occur across substantially the entire strand thickness, wherein the characteristic interstitial dimension of the material is greater than about 7u and the strand thickness is determined from the following relationships:

$$\ln (\text{strand diam}) \leq 2.28 \times 10^{-2} (\text{CID}) - 4.36$$

$$\text{for CID} > 7u, \leq 120u$$

$$\ln (\text{strand diam}) \leq 6.98 \times 10^{-2} (\text{CID}) - 9.94$$

$$\text{for CID} \geq 120u$$

where: CID = characteristic interstitial dimension (microns)

ln = natural logarithm

strand diameter is expressed in inches

2. Article as in Claim 1 wherein the porosity is greater than about 30%.

3. Article as in Claim 2 wherein the matrix tensile strength of the material is greater than about 20,000 psi.

4. Article as in Claim 2 wherein the matrix tensile strength of said material is greater than about 40,000 psi.

5. Article as in Claim 3 or 4 wherein the strand thickness is less than 0.08", the characteristic interstitial dimension is about 74u, the matrix tensile strength of the material is about 74,000 psi, and the porosity of the material is about 81%.

6. Article as in Claim 3 or 4 wherein the strand thickness is about 0.026", the characteristic interstitial dimension is about 74u, the matrix tensile strength of the material is about 74,000 psi, and the porosity of the material is about 81%.

7. Article as in Claim 3 or 4 wherein the matrix tensile strength of the material is about 87,000 psi, the strand thickness is less than about 0.010", the characteristic interstitial dimension is about 11u, and the porosity of the material is about 50%.

8. Article as in Claim 3 or 4 wherein the matrix tensile strength of the material is about 87,000 psi, the thickness of each strand is about 0.0010", the characteristic interstitial dimension is about 11u, and the porosity of the material is about 50%.

9. Article of manufacture for use as a tensile load-bearing tissue prosthesis for connection between tensile force-applying tissues

comprising, in the portion wherein attachment to the tensile force-applying tissue is required, a plurality of longitudinally adjacent parallel non-adhering strands of microporous polytetrafluoroethylene material having interconnecting voids defined by nodes and fibrils, the thickness of each of said strands being chosen in relation to the microstructure of said material such that tissue ingrowth can occur across substantially the entire strand thickness, wherein the characteristic interstitial dimension of the material is greater than about 7u and the strand thickness is determined from the following relationships:

$$\ln \text{(strand diam)} \leq 2.28 \times 10^{-2} \text{(CID)} - 4.36$$

for CID > 7u, $\leq$ 120u

$$\ln \text{(strand diam)} \leq 6.98 \times 10^{-2} \text{(CID)} - 9.94$$

for CID $\geq$ 120u

where: CID = characteristic interstitial dimension (microns)

ln = natural logarithm

strand diameter is expressed in inches

article further including means for distributing the tensile load among the individual strands when the prosthesis is intended to be passed over a radius.

10. Article as in Claim 9 wherein said load distributing means includes said plurality of strands being twisted about the tensile load direction.

11. Article as in Claim 10 wherein the angle of twist is about 180°.

12. Article as in Claim 9 wherein said load distributing means includes the strands being loosely braided.

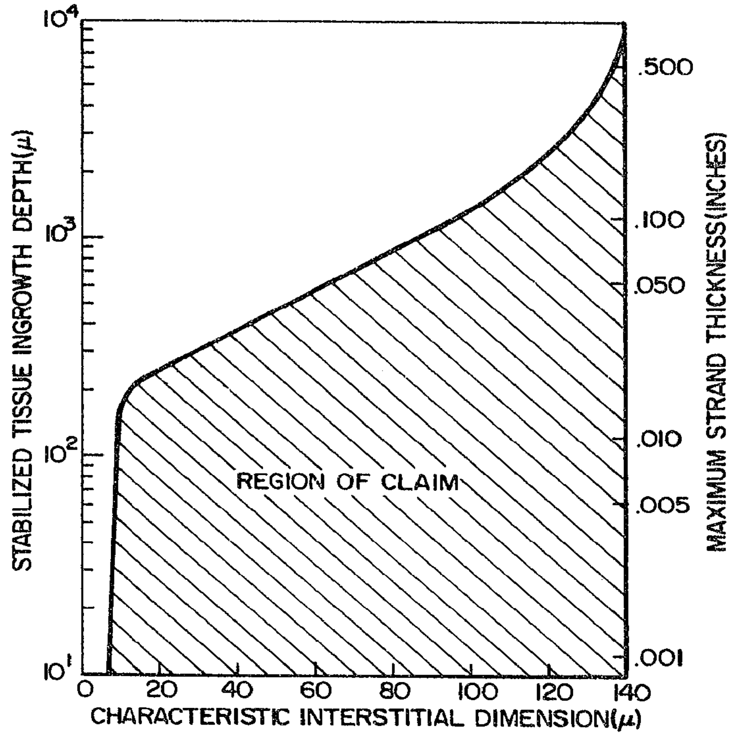

FIG. I

Gowling & Henderson

1205602
10-2

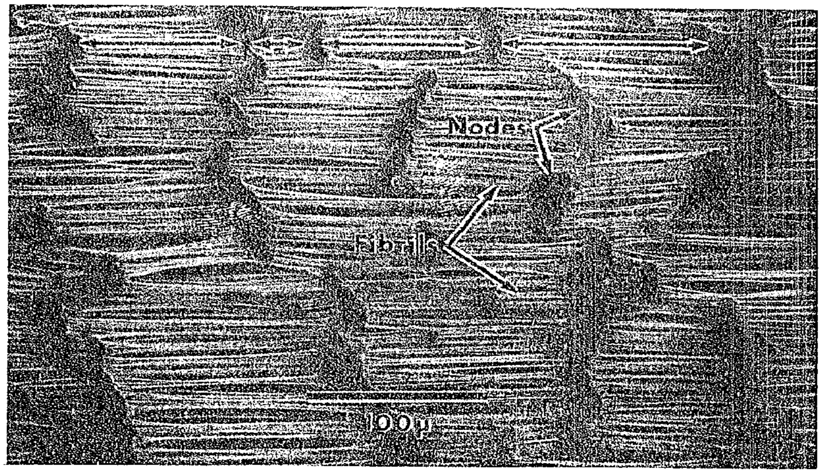

FIG. 2

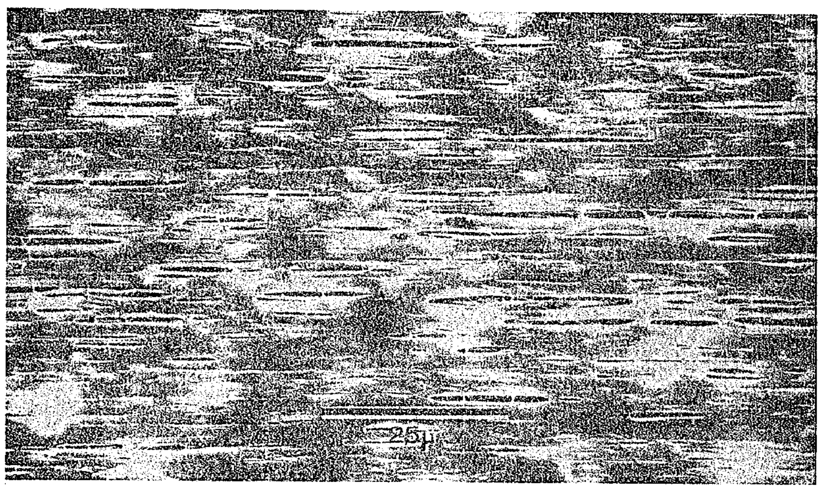

FIG. 3

Gowling & Henderson

1205602
10-3

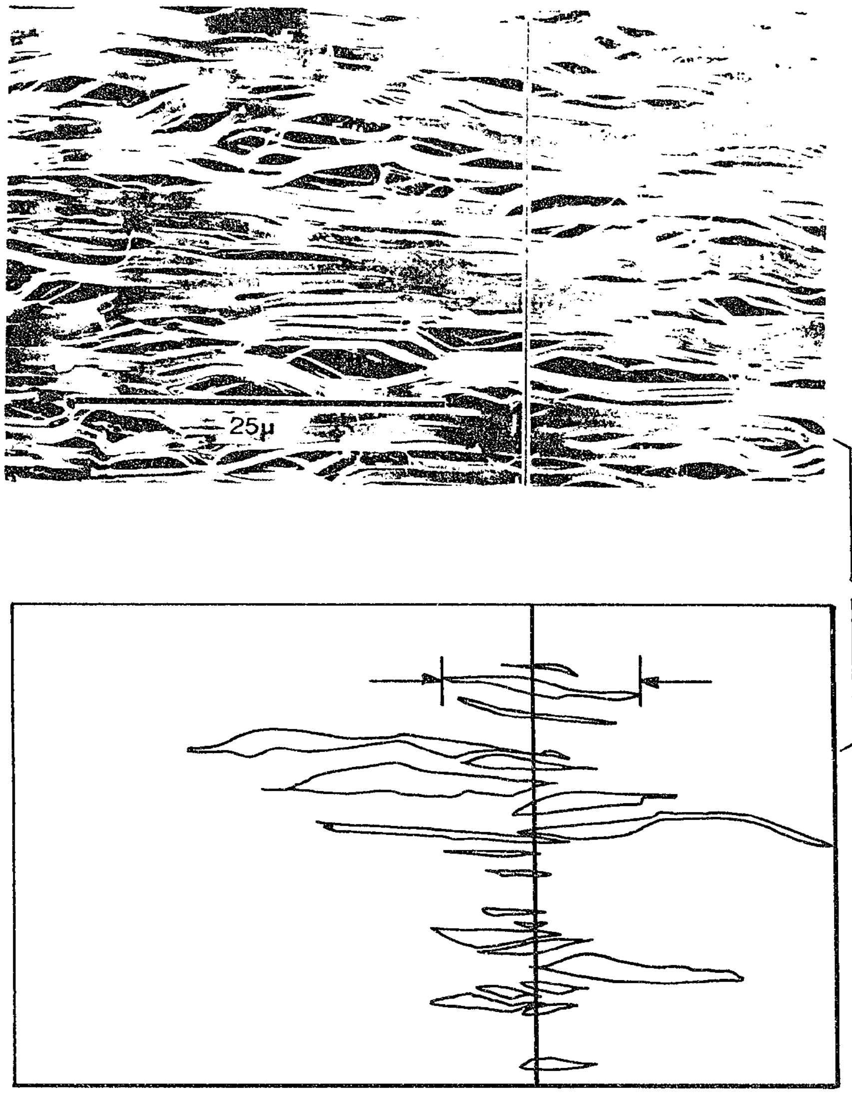

FIG. 4

Gowling & Henderson

1205602
10-4

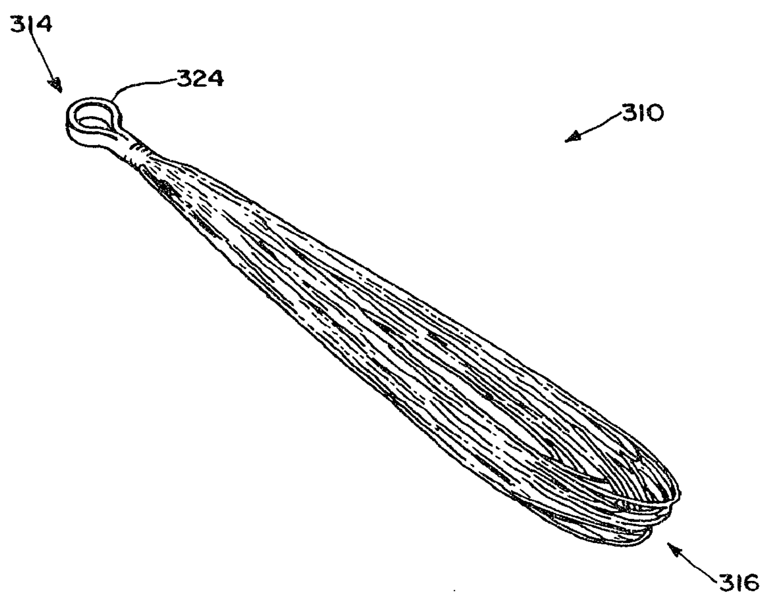

FIG. 5

Gowling & Henderson

1205602
10-5

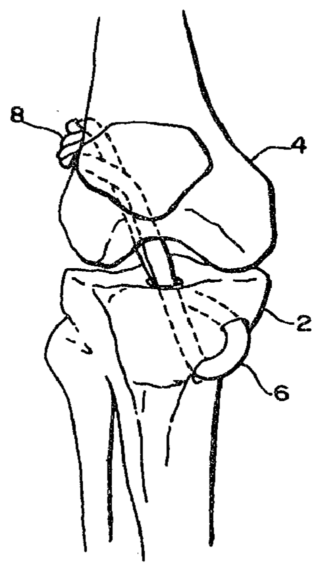

FIG. 6

Gowling & Henderson

1205602
10-6

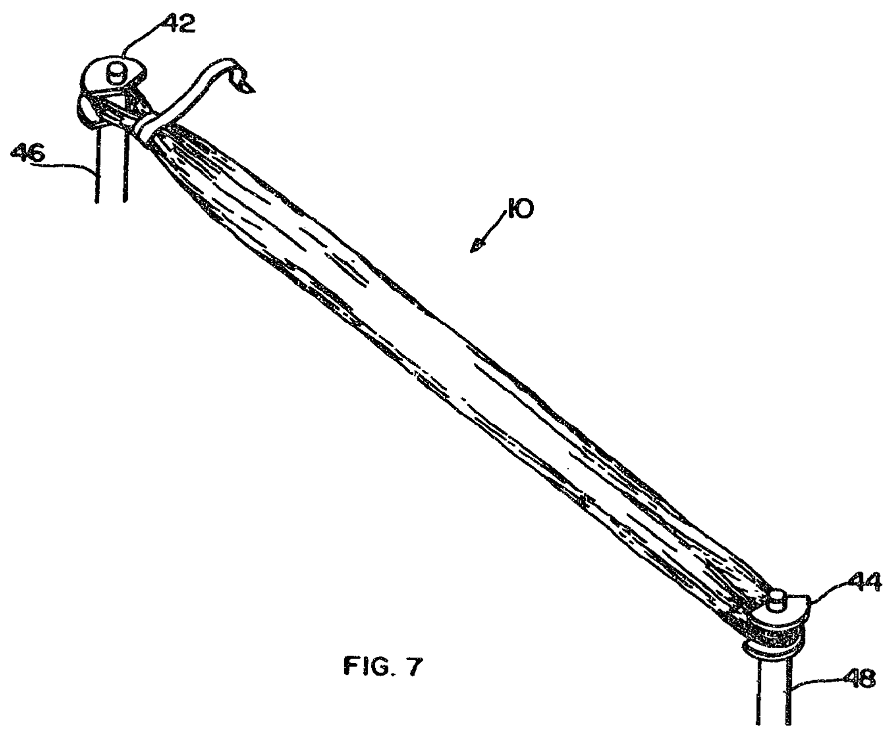

FIG. 7

Gowling & Henderson

1205602

10-7

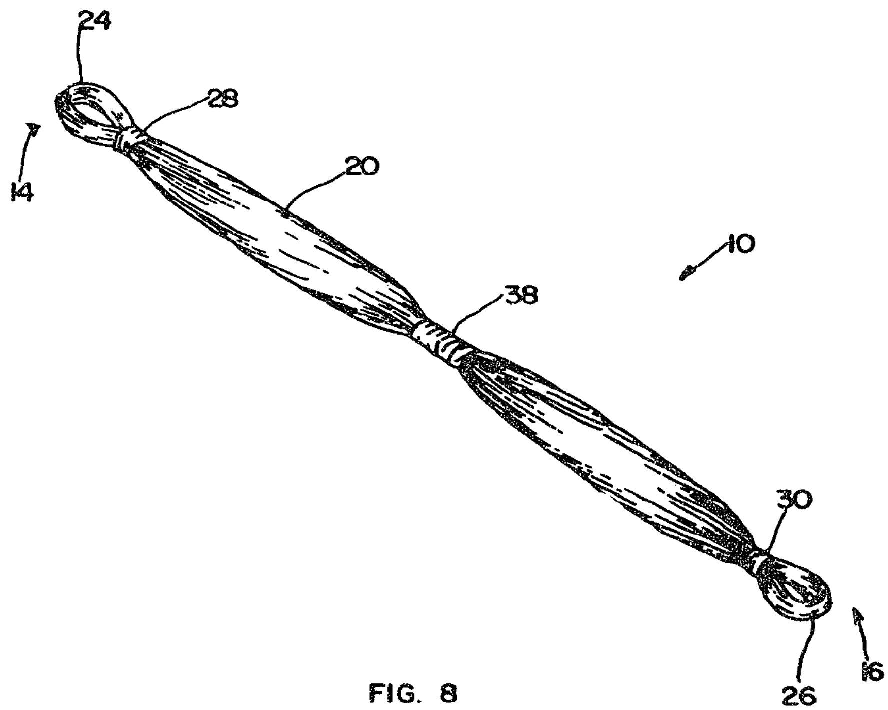

FIG. 8

Gowling & Henderson

1205602
10-8

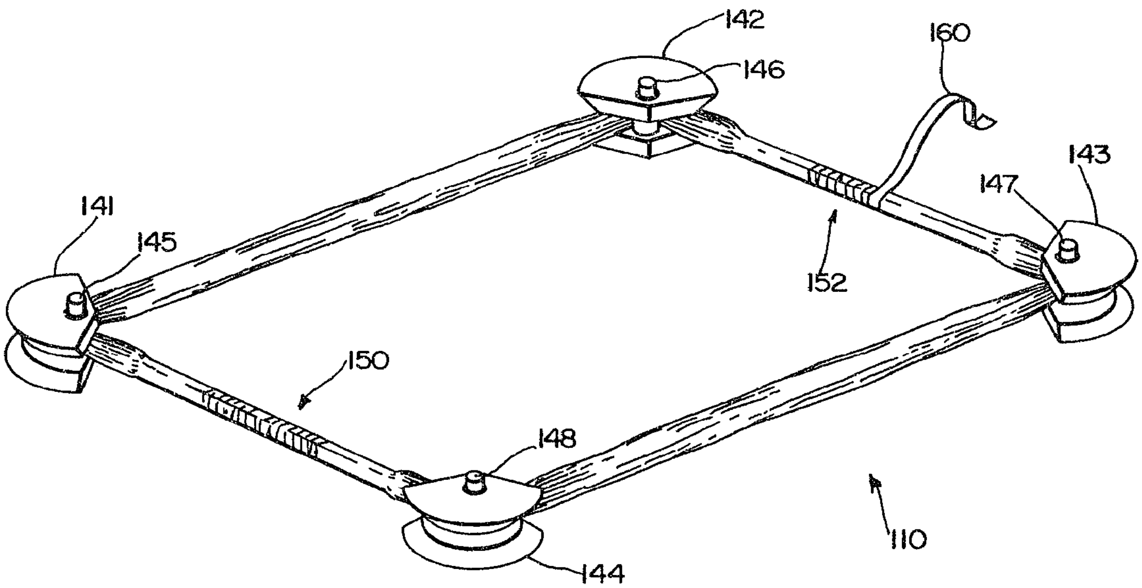

FIG. 9

Gowling & Henderson

1205602

10-9

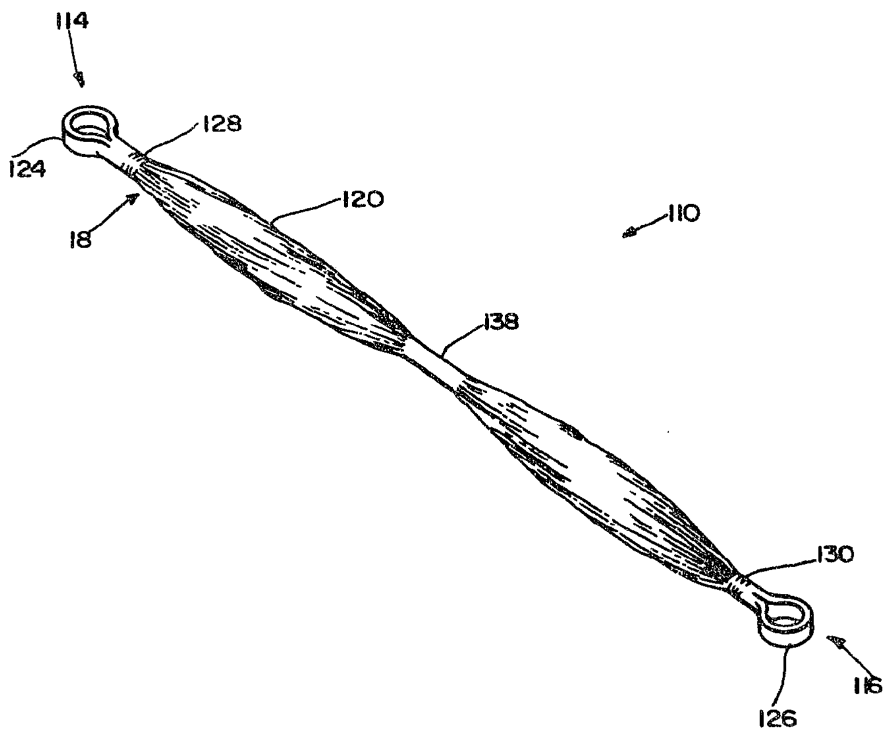

FIG. 10

Gowling & Henderson

1205602
10-10

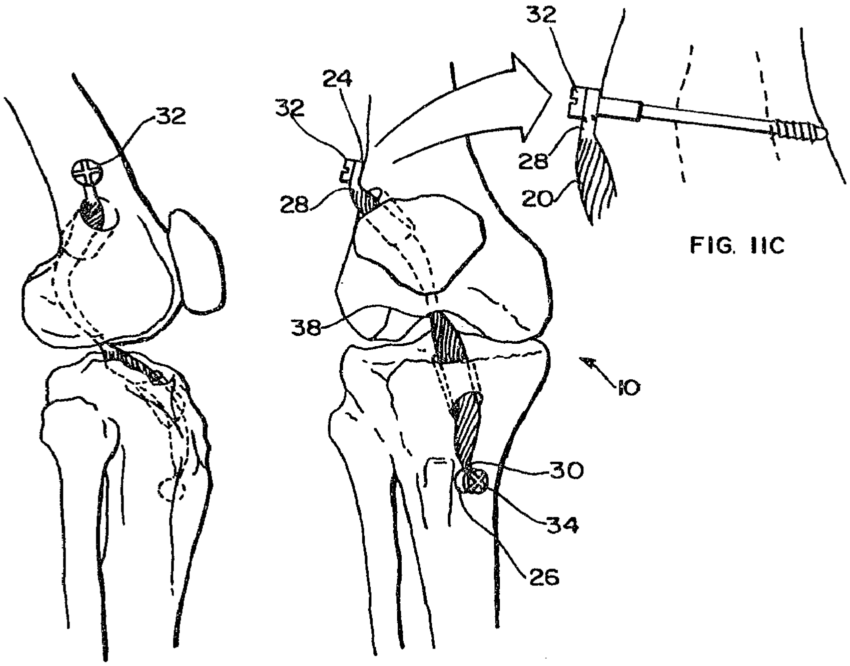

FIG. 11B

FIG. 11A

FIG. 11C

Gowling & Henderson